Large retrospective databases provide valuable information to examine adverse events associated with PN, which can be reliably identified and studied. Both sensitivity analyses and model validation added credibility to our approach.

RESPIRATORY-RELATED DISORDERS – Clinical Outcomes Studies

PRS1

A COMPARISON OF CLINICAL PROFILES, MEDICATION USE AND SYMPTOMOLOGY IN ASTHMA PATIENTS PRESCRIBED LOW/MODERATE DOSE FLUTICASONE PROPIONATE/SALMETEROL OR MODERATE/HIGH DOSE FLUTICASONE PROPIONATE

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OBJECTIVES: National asthma treatment guidelines recommend the use of low dose ICS plus a LABA or moderate to high dose ICS as the preferred treatment for moderate asthma. The purpose of this study was to determine if physicians prescribe low/moderate dose fluticasone propionate/salmeterol (FSC) or moderate/high dose fluticasone propionate (FP) to subjects with similar asthma clinical profiles, medication use, and symptomology. **METHODS:** This was a retrospective observational study using medical, pharmacy, and enrollment information from a large, US managed care plan and linked medical chart data comparing 3 years of baseline characteristics and medication treatment patterns in adult asthma patients initiating FSC or FP. Data acquired from medical and pharmacy claims included provider specialty, baseline asthma medication resource use, occurrence of spirometry testing, and Deyo-Charlson co-morbidity score. A random sample of medical charts (n = 460) was abstracted for baseline symptomology. **RESULTS:** A total of 32,189 subjects (average age: 46.6 [±14.4] years; 64% female) with an asthma diagnosis and initiating FSC or FP were identified from 1/1/06-12/31/07. Baseline co-morbidity scores were similar in FSC and FP patients (1.02 (1.31)) vs. 1.11 (1.50); p = 0.488). A greater proportion of patients receiving FSC had a baseline spirometry compared to FP patients (32.6% vs. 20.4%; p = 0.003) while. Shortness of breath was reported significantly more often for FSC (48.7% in FSC vs 38.3% in FP; p = 0.024). Other asthma symptoms were reported a similar rate across both groups and no significant differences in baseline use of other asthma medications were observed. **CONCLUSIONS:** Few significant differences in either claims history or asthma symptomology were observed between patients prescribed low/moderate dose FSC or moderate/high dose FP for the first time. Overall, physicians seem to be prescribing low/moderate dose FSC and moderate/high dose FP to similar asthma patients in alignment with national asthma treatment guidelines.

PRS2

A NOVEL METHODOLOGY FOR MEASURING THE INFLUENCE OF COMORBIDITY IN HEALTH OUTCOME STUDIES

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OBJECTIVES: In most studies, the influence of comorbidity is modelled additively as the number of comorbidities present or by an index (such as Charlson's) chosen without regard to the outcome of interest. We question these approaches with a novel methodology noting that: outcome may not be associated linearly with comorbidity count, the weights combining a set of binary comorbidities need not be positive (i.e. hypothesis (B) that outcome worsens with increasing comorbidity may be false), and our ability to identify specific interactions influencing prognosis is lost **METHODS:** We analyzed a retrospective cohort of 3332 patients, aged 50+ in the UK General Practice Research Database diagnosed with COPD between 1990 and 1998, and with a first COPD hospitalisation. Some 17 binary comorbidities were analysed in relation to risk of mortality and re-hospitalisation. We tested the null hypothesis (A), that comorbidity was similar in each layer of the two outcomes, crudely and adjusting for age and sex. Our methodology relies on logistic and log-linear modelling strategies for multidimensional contingency tables **RESULTS:** For both outcomes, hypothesis (A) was rejected (p < 0.001). Although comorbidity was found to influence death and rehospitalisation, the patterns of influence on the two outcomes were not similar and there were some with negative influence (i.e. comorbidities more frequent among survivors or those not rehospitalised); several significant 2-way interactions were revealed. Whilst most significant interactions were positive (especially for re-hospitalisation) there was negative interaction for death (e.g. peripheral vascular disease and CVD were more frequent among survivors), thus rejecting hypothesis (B) **CONCLUSIONS:** The use of these modelling approaches, in addition to or in place of existing comorbidity indices, will improve our understanding of how comorbidity relates to disease natural history and outcomes of interest. The application of this method to understanding potential high risk patient strata in benefit/risk management planning is particularly appealing

PRS3

THE PREVALENCE OF COMORBID CONDITIONS IN U.S. PATIENTS DIAGNOSED WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

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OBJECTIVES: COPD is the 4th leading cause of death among U.S. adults. Retrospective observational studies, including outcomes research, can provide important comparative analyses to help identify optimal treatment patterns and therapies. However, such comparisons often require multivariate analysis, propensity score matching, a comorbidity index or other methods to adjust for differences in patient characteristics. Rates reported in clinical trials often vary significantly from those observed in clinical practice. Using recent, real-world data this study was designed to identify the frequency of diagnosed comorbid conditions in the COPD population and serve as a research reference for future comparative studies. **METHODS:** Private practitioner medical claims (CMS1500 records) from SDI Health's data warehouse were extracted for the period November 1, 2007 to October 21, 2008. Patients were indexed to their first observed COPD diagnosis during the study period. Qualifying patients had 2 or more claims for COPD; a valid age and gender; and were observed in the dataset for 12 months or more from their index date. Patients could be diagnosed with COPD prior to the study period or new to the condition. Comorbid conditions of interest were defined a priori. As possible, MEDRA codes used in clinical trials were cross-walked to corresponding ICD-9 codes. All payer types were included. **RESULTS:** Of the 751,794 qualifying study patients, the mean age was 67.5 years (STD+/–13) and 55.4% were female. The 1 year prevalence of comorbid conditions observed was: Supraventricular Arrhythmia13.2%, Atrial Fibrillation 9.7%, Depression 9.0%, Suicide 0.1%, Insomnia 4.1%, Ischemic disease (ATPC composite) 28.8%, Metabolic Syndrome 0.4%, and Other Mental Health conditions 14.7%. **CONCLUSIONS:** Patients with COPD have a variety of significant comorbid conditions observed in real-world, clinical practice. These factors can affect findings of comparative studies and are important considerations for future research.

PRS4

ESTIMATION OF MORTALITY RISKS ATTRIBUTABLE TO COMORBIDITY IN COPD

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OBJECTIVES: Even in late-phase trials, it is common practice to exclude patients with certain pre-existing conditions based primarily on clinical knowledge. Such exclusions can result in low recruitment and associated consequences. Comorbidities are common in chronic diseases and for a specific outcome, data on the risk attributable to each can help inform decisions on inclusion/exclusion. We present a graphical methodology for obtaining such empirical evidence **METHODS:** A retrospective cohort of 23,881 patients aged 50+ in the UK-GPRD at incident COPD diagnosis between 1990–1998 provided our setting. Each death patient was matched to as many survivors from the same practice as possible, of same age, sex and COPD duration. Some 18 binary comorbidities measured at the time of death were analysed in relation to mortality. Using conditional logistic regression model, we estimated hazard ratio (HR) for each comorbidity, adjusted for key baseline characteristics as well as its prevalence at the time of COPD diagnosis (PRC) and in 1998 (PR98). We plotted the HRs against the PRCs and PR98s as graphs A and B respectively **RESULTS:** Some 2,938 dead patients were matched to 5792 survivors. The most contributors to mortality risk were-CHF (HR: 3.3 p < 0.0001; PRC = 15.6%, PR98 = 18.2%), lung cancer (HR: 20.4 p < 0.0001; PRC = 0.7%, PR98 = 1.2%), other cancers (HR: 12.3 p < 0.0001; PRC = 0.7%, PR98 = 1.8%), and CVD (HR: 4.1 p < 0.0001; PRC = 3.2%, PR98 = 4.7%). Newly diagnosed moderate/severe liver disease (<1 year) was rare but with a high risk (HR: 16.7 p = 0.014; PRC = 0.3%, PR98 = 0.4%), suggesting such patients could be excluded in a trial. In contrast, diabetes-without-complication was common but with little effect on risk (HR: 1.2 p > 0.37; PRC = 5.1%, PR98 = 7.2%), suggesting such patients could be included in a trial with recruitment concerns **CONCLUSIONS:** The information provided by the tool can assist trial planning on sample size estimations as well as improve our understanding of how comorbidities influence outcome

PRS5

COMORBIDITIES, QUALITY OF LIFE, AND HEALTH CARE ACCESS BY RISK COHORT CHARACTERISTICS OF PEOPLE CALCULATED USING FRAMINGHAM RISK PERCENT FROM THE US NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY (NHANES)

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OBJECTIVES: To examine characteristics of demographic, clinical conditions, comorbidities, quality-of-life and health care access by risk cohorts calculated using Framingham risk percent in a United States (US) national sample. **METHODS:** Characteristics of 3 cohorts were defined by Framingham low risk (<10%), middle risk (10%~20%) and high risk (>20%) and compared by mean and proportions of respondents using 2005–2006 National Health and Nutrition Examination Survey (NHNES) data. **RESULTS:** The sample comprised 1,751 persons aged ≥20 years with all necessary analysis variables (age, total cholesterol, smoking status, HDL, systolic blood pressure, and hypertension treatment) used to calculate Framingham 10-year risk percent. Compared to respondents in low and middle risk cohorts, the high risk cohort was older (61 years old vs. 42 and 60), more male (92% vs. 45% and 84%), and reported less years of education, less married (71% vs. 32% and 32%), more smokers (57% vs. 49% and 52%), higher levels of hypertension treatment (64% vs. 19% and 51%) and a higher proportion of overweight and obese (76% vs. 61% and 72%). More high risk cohort people reported diagnoses of hypertension (60% vs. 24% and 45%), diabetes (15% vs. 5% and 11%), asthma (47% vs. 32% and 41%), and cancer (15% vs. 7% and 13%). Less of the high risk cohort reported "good health" conditions than those in low and middle risk cohorts (70% vs. 84% and 80%). The high risk cohort was more likely to report public insurance (54%) than either low (18%) or middle risk (46%) cohorts. **CONCLUSIONS:** An NHANES-based